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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,993	11/04/2003	Charles R. Saikley	TS-02-89	6633

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

ED

Office Action Summary	Application No. 10/701,993	Applicant(s) SAIKLEY ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-51 is/are pending in the application.
- 4a) Of the above claim(s) 36-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendments filed on 10/03/2006 and 01/16/2007, amendment(s) to the specification, amended claim(s) 21, 22, 27-30, and 34-35, canceled claim(s) 1-20, and withdrawn claim(s) 36-51 is/are acknowledged. The current rejections of the claim(s) 21-35 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Objections

2. Claim 21 is objected to because of the following informalities: the positive recitation of "therein; and" in line 3 appears to be a typographical error and may render the claim indefinite for failing to be a complete sentence having no grammatical errors. Appropriate correction is required.

3. Claim 21 is objected to because of the following informalities: the positive recitation of "with mechanical components" in line 8 appears to lack antecedent basis and may render the claim indefinite. Moreover, the Examiner notes the structural limitation "mechanical components" is a broad limitation that may render the claim indefinite for omitting essential structural relationships between the mount block and housing. Appropriate correction is required.

4. Claim 21 is objected to because of the following informalities: the positive recitation of "the bodily fluid sample location" in lines 9 and 10 appears to lack

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antecedent basis and may render the claim indefinite. Appropriate correction is required.

5. Claims 21 and 22 are objected to because of the following informalities: the term "approximately" is a relative term that appears to render the claim(s) indefinite. The term "approximately" is not defined by the claim(s), the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The location of the test strip with regards to the bodily fluid sample is unclear.

6. Claim 22 is objected to because of the following informalities: the term "substantially" is a relative term that appears to render the claim(s) indefinite. The term "substantially" is not defined by the claim(s), the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The alignment relationship between the cutting edge and test strip is unclear.

7. Claim 24 is objected to because of the following informalities: the term "substantially" is a relative term that appears to render the claim(s) indefinite. The term "substantially" is not defined by the claim(s), the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The alignment relationship between the first and second axes is unclear.

8. Claims 27 and 28 are objected to because of the following informalities: the positive recitation of "inch" appears to be a typographical error and may render the

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claim indefinite for failing to be a complete sentence having no grammatical errors. It is noted Applicant may have intended it to read "inches". Appropriate correction is required.

9. Claims 27-29 are objected to because of the following informalities: the positive recitation of varying units of measure is informal. Appropriate correction is required.

10. Claim 28 is objected to because of the following informalities: the term "substantially" is a relative term that appears to render the claim(s) indefinite. The term "substantially" is not defined by the claim(s), the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The location of the fill channel of the test strip with regards to the bodily fluid sample is unclear.

11. Claim 29 is objected to because of the following informalities: the term "approximately" is a relative term that appears to render the claim(s) indefinite. The term "approximately" is not defined by the claim(s), the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The magnitude of the trajectory is unclear.

12. Claim 30 is objected to because of the following informalities: the positive recitation of "the captured portion" in line 2 appears to lack antecedent basis and may render the claim indefinite. Appropriate correction is required.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the cooperative relationship between the mount block and the positively recited procedural limitation following said mount blocks definition. The ambiguous section of the claim appears to be how the mount block and mechanical components are related to "moving the test strip along a trajectory such that a reagent receiving portion of the test strip comes to rest approximately at a center of the body fluid sample" "without moving the housing relative to the bodily fluid sample location".

Claim Rejections - 35 USC § 101

16. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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17. Claim 29 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is directed to a naturally occurring phenomenon (i.e. the human body). The claim positively recites the structural limitation "a patient's skin" (i.e. the human body) within the scope of the invention.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

18. Claims 21-24 and 26-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al (US 5,279,294) as broadly as *structurally* claimed.

19. For claim 21, Anderson et al discloses a device (10) for obtaining and testing a bodily fluid sample, comprising:

- a housing (16 and 18) having a first aperture (the slot between guide bars 48 and 50, column 6 lines 56-60) provided therein;
- a lancing device (14) operatively coupled to said housing that obtains a sample by advancing through said first aperture and pierces a bodily fluid sample location and is withdrawn to provide access to the sample by a test strip (12); and
- a mounting block (44 and 46) coupled with mechanical components (48 and 50) within the housing for coupling the test strip thereto,
- wherein the test strip is capable of moving along a trajectory (the arrows as best seen in Figure 4) such that a reagent receiving portion (72) of the test strip comes to

rest approximately at a center of the bodily fluid sample whilst the housing is capable of not moving relative to the sample.

20. For claim 22, Anderson et al discloses the device of claim 21, wherein the lancing device (14) comprises a cutting edge that is substantially aligned with the test strip (12), although withdrawn following lancing to provide said sample, when the test strip is received in the housing and moved to approximately said center of the sample (as best seen in Figures 4, 13, 14f, 14g, and 14h).

21. For claim 23, Anderson et al discloses the device of claim 21, wherein the lancing device is operatively coupled to said housing by a spring mechanism (68).

22. For claim 24, Anderson et al discloses the device of claim 21, wherein the lancing device comprises a body having a first axis, and a sharp operatively connected to the body, wherein the sharp has a second axis that is substantially perpendicular to the first axis (as best seen in Figures 14d and 14i).

23. For claim 26, Anderson et al discloses the device of claim 21, wherein the lancing device is of a construction sufficient to pierce tissue of a patient (column 3 lines 40-42).

24. For claim 27, Anderson et al discloses the device of claim 21, wherein when the test strip is received in the housing, and after said lancing and withdrawing of the lancing device, the test strip is capable of being moved from a received position to a sample-contacting position within 0.010 inches of said center of the sample, via a user as best seen in Figure 13.

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25. For claim 28, Anderson et al discloses the device of claim 27, wherein when the test strip is in the sample-contacting position, a fill channel (70) of the test strip is capable of being substantially aligned with the sample within 0.005 inches of said center of said sample, via a user as best seen in Figure 13.

26. For claims 29, 34, and 35, Anderson et al discloses the device of claim 21, wherein the trajectory is capable of comprising a travel distance of approximately 1 mm and capable of comprising an approach angle between 35 – 65 degrees.

27. For claim 30, Anderson et al discloses the device of claim 21, wherein the physiological property that is determined from the sample comprises a glucose level, a carbohydrate level, a hemoglobin level, or a glycated hemoglobin level (column 4 lines 24-30).

28. For claim 31, Anderson et al discloses the device of claim 21, further comprising a controller (130) operatively coupled to the housing for controlling operation of the lancing device

29. For claim 32, Anderson et al discloses the device of claim 21, further comprising an input unit (30) operatively coupled to the housing for operating the lancing device.

30. For claim 33, Anderson et al discloses the device of claim 21, further comprising a controller (a hand as best seen in Figure 13) operatively coupled to the housing for controlling movement of the test strip when the test strip is received in the housing.

31. For claim 34, Anderson et al discloses the device of claim 21, further comprising a display (24) operatively coupled to the housing for displaying the result.

32. For claim 35, Anderson et al discloses the device of claim 34, further comprising a controller (116) operatively coupled to the housing for controlling the display.

Claim Rejections - 35 USC § 103

33. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

34. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in view of Yuzhakov et al (US 2003/0028125 A1). Anderson et al discloses the claimed invention except for the lancing device comprising a sharp with at least two points. Yuzhakov et al teaches a device for obtaining and testing a bodily fluid sample comprising a plurality of sharp points as best seen in Figures 3a and 3b. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sample obtaining and testing device as taught by Anderson et al, with the sample obtaining and testing device as taught by Yuzhakov et al for the purpose of piercing the skin of a test subject via a plurality of sharp points to increase the sample size for sufficient testing volume and accuracy.

Response to Arguments

35. Applicant's arguments filed 10/03/2006 with respect to claims 21-35 have been considered but are moot in view of the new ground(s) of rejection. However, the Examiner notes the following:

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36. In response to applicant's argument that for claim 21 Anderson et al does not disclose, teach, or fairly suggest a movable test strip and in the alternative a stationary test strip with a nearby reagent pad, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

37. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a movable test strip with a nearby reagent pad) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

38. In response to applicant's argument that for claim 33 Anderson et al does not disclose, teach, or fairly suggest a movable test strip and in the alternative a stationary test strip with a nearby reagent pad, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

39. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JH

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